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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/782,594 | 02/12/2001 | John R. Bianchi | RTI- 112R | 9490 |

7590 11/04/2003
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EXAMINER

PREBILIC, PAUL B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3738

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/782,594

Applicant(s)

BIANCHI ET AL.

Examiner

Paul B. Prebilio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 1-25, 43 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-42, 44 and 46-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g. 6) ☐ Other:

Specification

The disclosure is objected to because of the following informalities:

Upon review of the pending claims it was determined that there was no claim 48. Therefore, the Examiner renumbered claims 49-61 as claims 48-60, respectively so that the claims were consecutively ordered. Applicants are respectfully requested to renumber their claim set accordingly.

Appropriate correction is required.

Election/Restrictions

Claims 1-25 and 43 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 23 filed August 25, 2003.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Va. Claims 26-42, 44, and 46-60, drawn to the composite bone graft, classified in class 623, subclass 23.51.
- Vb. Claim 45, drawn to method of making a composite bone graft, classified in class 264, subclass 405.

The inventions are distinct, each from the other because of the following reasons:

Inventions Va and Vb are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

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(MPEP § 806.05(f)). In the instant case, the product as claimed could be made by a different process such as shaping the component parts prior to assembling them into a unit.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Donald Pochopien on October 29, 2003 a provisional election was made with traverse to prosecute the invention of Group Va, claims 26-42, 44, and 46-60. Affirmation of this election must be made by applicant in replying to this Office action. Claim 45 as well as previously withdrawn claims 1-25 and 43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The drawings are objected to because in Figures 6, 7, 13, 14, 18, 20C, 21D, 21E, and 22D, the crosshatching indicates metal not bone components; see MPEP 608.02.

In addition, the formal drawings filed August 8, 2001 do not contain a legend labeling the first drawing as Figure 1.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The abstract of the disclosure is objected to because it does not adequately describe the presently claimed invention. Correction is required. See MPEP § 608.01(b).

Information Disclosure Statement

The information disclosure statement filed October 9, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The copies may have been lost by the USPTO so the Examiner retrieved and reviewed all but one document; see page 2 of the enclosed copy of the PTO-1449. Applicants are respectfully requested to provide a copy thereof in response to this office action; i.e. a copy of the GIE et al (article).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38, 41, 42, and 53-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 38, the Markush listing is confusing and unclear because of the multiple ands and ors. It is not clear where the listing ends.

With regard to claim 41, lines 4-7, the terminology "plate-like" is considered to be indefinite because it is not clear what would fall within the scope thereof.

With regard to claim 42, "plate-like" is also used in this claim and is indefinite for the reasons that claim 41 was said to be indefinite.

With regard to claims 53-55, line 2, the term "peg-like" is considered to be indefinite because it is not clear what falls within the scope thereof.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-42, 44, and 46-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al (US 6,200,347). Anderson anticipates the claim language where the bone portions as claimed are the bone grafts (16 and 17 of Figure 7 or elements 2 and 4 of Figure 1) and the pins of Anderson are threaded and do not contain adhesive (see column 5, lines 43-50); see also column 19, line 62 to column 20, line 36 and column 5, lines 1-8.

With regard to claims 50 and 51, Applicants are directed to see Figures 41 and 42C as well as column 26, line 17 et seq.

Claims 26-31, 33-35, 37, 38, 40, 42, 49, 50, 53-55, and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Yaccarino, III (US 6,025,538). Yaccarino anticipates the claim language where the first portion as claimed is the first bone member (22) of Yaccarino (see Figure 6 and column 4, line 35 to column 5, line 47 as well as column 7, lines 1-10). The second bone portion as claimed is the second bone member (24) of Yaccarino.

With regard to claim 31, the third bone portion is one of the pins and the connector is the other pin; see Figure 8.

With regard to claims 49, 50, 53, and 54, the pins of Yaccarino provide the interlocking required by these claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilio whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a stylized flourish at the end.

Paul Prebilic
Primary Examiner
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